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10/801,297	03/17/2004	Lazonia Victoria Jordan		3031

7590
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06/04/2007

EXAMINER

VAKILI, ZOHREH

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/801,297	Applicant(s) JORDAN, LAZONIA VICTORIA	
	Examiner Zohreh Vakili	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-11 are presented for examination.

Any cited U.S. Patent can be found at www.uspto.gov.

Objection to the Claims

Claim 1 is not entirely clear as to whether it is a composition or a method. For the basis of examination claim 1 is interpreted as a method.

Claim 1 is objected to for not complying with the format requirements of 37 C.F.R. 1.75. A claim should identify the statutory category of invention (i.e., process, machine, manufacture or composition of matter; as defined under 35 U.S.C. 101) to which the claimed invention is directed and also include a recitation of each and every element, step and /or relationship which constitutes that portion of the invention that Applicant considers to be the novel contribution to the art.

The Examiner has cited U.S. Patent No. 5614209 to Ford to demonstrate proper claim construction and has included a copy of Rule 37 C.F.R. 1.75 from the MPEP at §608.01(i), which defines claim requirements.

"37 CFR 1.75. Claims

(a) The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery.

(b) More than one claim may be presented provided they differ substantially from each other and are not unduly multiplied.

(c) One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. Any dependent claim which refers to more than one other claim ("multiple dependent claim") shall refer to such other claims in the alternative only. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim.

For fee calculation purposes under § 1.16, a multiple dependent claim will be considered to be that number of claims to which direct reference is made therein. For fee calculation purposes, also, any claim depending from a multiple dependent claim will be considered to be that number of claims to which direct reference is made in that multiple dependent claim. In addition to the other filing fees, any original application which is filed with, or is amended to include, multiple dependent claims must have paid therein the fee set forth in § 1.16(d). Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of each of the particular claims in relation to which it is being considered.

(d) (1) The claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description (See § 1.58(a).)

(2) See §§ 1.141 to 1.146 as to claiming different inventions in one application.

(e) Where the nature of the case admits, as in the case of an improvement, any independent claim should contain in the following order, (1) a preamble comprising a general description of all the elements or steps of the claimed combination which are conventional or known, (2) a phrase such as “wherein the improvement comprises, ” and (3) those elements, steps and /or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion.

(f) If there are several claims, they shall be numbered consecutively in Arabic numerals.

(g) The least restrictive claim should be presented as claim number 1, and all dependent claims should be grouped together with the claim or claims to which they refer to the extent practicable.

(h) The claim or claims must commence on a separate physical sheet or electronic page. Any sheet including a claim or portion of a claim may not contain any other parts of the application or other material.

(i) Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation.”

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Guidance for the proper manner and form of making amendments to the claims can be found in the MPEP at 37 C.F.R. 1.121, which is copied below for Applicant's clarification.

Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) Claim listing. All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) When claim text with markings is required. All claims being currently amended in an amendment paper shall be presented in the claim listing,

indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) When claim text in clean version is required. The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, i.e., without any underlining.

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- (4) When claim text shall not be presented; canceling a claim.
 - (i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."
 - (ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.
- (5) Reinstatement of previously canceled claim. A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The statements within the parentheses do not make it clear as to whether the component is required, is an alternative name or is an additional component for administration. For example, tabebuia heptaphylla is recited, but it is not clear as to whether this is an alternative name or an additional component.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the prevention of vaginal yeast infection. The specification reasonably provides enablement for the control and management of yeast infection, but clearly not the prevention of. The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) As to undue experimentation.

The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art;
- 4) the relative skill of those in the art;
- 5) the amount of direction or guidance presented;
- 6) the presence or absence of working examples;
- 7) the quantity of experimentation necessary;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

- 1) the nature of the invention; the invention is directed to a method for preventing vaginal yeast infection.
- 2) the breadth of the claims; the scope of the method claims include the prevention

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of vaginal yeast infection.

3) the predictability or unpredictability of the art; the art does not enable a person of ordinary skill in the art to make and use the claimed invention without resorting to undue experimentation. The burden of enabling one skilled in the art to prevent vaginal yeast infection would be much greater than that enabling the treatment. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing yeast infection. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active ingredients for preventing vaginal yeast infection.

No experimental evidence or mechanism of action for supporting preventing vaginal yeast infection using the specified actives would actually prevent all vaginal yeast infection by simply administering, by any method, an amount of the claim specified active agents. The specification fails to enable one of ordinary skill in the art to practice the presently claimed method for preventing the risk of vaginal yeast infection.

The term "prevention" or "preventing" circumscribes methods of treatment having absolute success. Since absolute success is not as of yet reasonably possible with most diseases/disorders, the specification is viewed as lacking an adequate enablement of where vaginal yeast infection may be actually prevented.

4) the relative skill of those in the art; the relative skill of those in the art of pharmaceuticals is high.

5) the amount of direction or guidance presented; the specification and the example

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does not provide any guidance in terms of preventing vaginal yeast infection.

6) the presence or absence of working examples; no working examples are provided for preventing yeast infection, for example in a patient, in the specification.

The applicant has not provided any competent evidence or disclosed any tests that are highly predictive for the preventative effects of the instant composition. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved".

See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

7) the quantity of experimentation necessary; the quantity of experimentation would be an undue burden to one of ordinary skill in the art and amount to the trial and error type of experimentation. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention and unpredictability of preventing yeast infection, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

In consideration of each of factors 1-7, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claims 1, 3, 4 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses a formulation for yeast infection, comprising of Acidophilus, Garlic, and Pau d'Arco which meet the written description and enablement provisions of 35 USC 112, first paragraph.

However, claims 1, 3, 4 and 8-11 are directed to encompass "natural ingredients", which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these "natural ingredients" meet the written description provision of 35 USC § 112, first paragraph because "natural ingredients" is such a large genus of compounds that the disclosure of the particular combination of, for example, the combination of agents claimed in present claim 2 is not a representative set of species of the genus. It has been held in patent law that disclosure of a representative set of species should be present to provide adequate written description of a highly variant genus. Further, Applicant has not given any direction as to how one would readily identify those natural ingredients with activity against vaginal yeast infections aside from those ingredients specifically named. The genus of "natural ingredients" is highly variant and encompasses a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*. (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116).

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed natural ingredients regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF’s were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In*

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re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”). Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Ford (US Patent No. 5614209), in view of Mayra-Makinen et al. taken with Steven Foster

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<http://www.umm.edu/altmed/ConsHerbs/PaudArcoch.html>, copyright 2004), further in view of Encyclopedia of alternative Medicine, Yeast Infection (<http://health.enotes.com/alternative-medicine-encyclopedia/yeast-infection>, Copyright 2000-2007) and Watson et al. (US Patent No. 6551628 B1).

Ford teach a pharmaceutical composition in the form of capsules, tablets, creams, foams, ointments, powders, suppositories or the like containing micro-encapsulated lactobacilli bacteria for oral, topical and intra-vaginal administration for the treatment or prevention of antibiotic associated diarrhea, skin and vaginal infections (see col. 1, lines 16-22). Generally speaking there is at least 10^3 viable micro-encapsulated lactobacilli in each gram or milliliter of the pharmaceutical composition of the invention. More preferably, the concentration of the lactobacilli bacteria in the delivery vehicle or pharmaceutical composition is in the range of approximately 10^3 to 10^{12} viable bacteria per gram, or per milliliter of the pharmaceutical composition, with the range of 10^5 to 10^{12} being even more preferred. In this regard it is noted that 10^{12} bacteria per gram or per milliliter essentially represents the highest number of lactobacilli bacteria which can be given in a gram or milliliter of material. The presently most preferred concentration of lactobacilli for topical or oral application is approximately 10^6 to 10^7 viable micro-encapsulated bacteria per milliliter or gram of composition (see col. 2col. 3, lines 1-14). The micro-encapsulated lactobacilli can be mixed with corn-starch, talcum or other suitable powder material. Creams, foams and ointments and conventional suppositories can be prepared, where, in addition to the active ingredient micro-encapsulated lactobacilli, fillers such as micro-crystalline

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cellulose, hydroxypropylmethyl cellulose, magnesium stearate, silicon dioxide, and lactose may be used (see column 8, lines 48-55). The encapsulated lactobacilli were given four times a day at the initiation of the antimicrobial therapy and were continued for three days after the antibiotic therapy was discontinued. All of these patients were given antibiotics for appropriate medical indications that were completely independent of this study. An oral consent was obtained and the potential risks and benefits of this study were explained in detail. The patients were treated with 10^6 encapsulated lactobacilli per dose that had been prepared according to Encapsulation Method B, which involved a poly-lysine base that was safe for oral administration. The preparation was given in a gelatin capsule filled with the encapsulated micro-organisms at the above dose (approximately 10^6 viable bacteria per capsule) (see col. 6, lines 54-67).

Mayra-Makinen et al. teach a probiotic combination comprising different combinations of lactobacilli, propionic acid bacteria, and/or bifidobacteria (see abstract). The invention can be used as such or in the form of capsules, pills or tablets, for example, manufactured in conventional processes of preparing pharmaceutical products. The combination of the invention may also be added to diverse edible products, such as foodstuffs, products of the beverage or confectionery industry, health-promoting products, natural products, etc. In the context of the present invention, products containing the combination of the invention, such as dairy products, particularly yogurts and other fermented milk products; cheeses and spreads; children's food; juices and soups; and capsules are preferred. A product in the form of

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a capsule usually only contains the probiotic combination, the prebiotic being consumed separately. The invention relates to a combination of probiotics, the combination comprising lactobacilli, propionic acid bacteria and/or bifidobacteria in various combinations. The probiotics are preferably combined with a suitable prebiotic to produce a synbiotic. The combination of the invention may be consumed as such or combined with a suitable foodstuff, such as a dairy product or a drink (see page 1, paragraph 1).

Foster teach Pau d'arco, or the inner bark of the *Tabebuia avellanedae* tree, is native to Brazil, where it is used traditionally to treat a wide range of conditions including candidiasis (a yeast infection of the vaginal tract (see page 1, overview).

Remedies for vaginal candidiasis include vinegar douches or insertion of a paste made from *Lactobacillus acidophilus* powder into the vagina. These remedies will make the vagina more acidic, and therefore, less hospitable to the growth of *Candida* (see claim 3). Fresh garlic (*Allium sativum*) is believed to have antifungal action, so incorporating into diet or inserting a peeled garlic clove wrapped in gauze into the vagina may be helpful. The insert should be changed twice daily. Some prescription drugs, particularly antibiotics, may disrupt the bacteria normally present in the intestine and vagina, causing the unpleasant symptoms of constipation, diarrhea, or vaginitis. Because *Lactobacillus acidophilus* is one such regular inhabitant that can prevent bacterial or yeast overgrowth, consumption of yogurt or *L. bacillus* capsules or tablets has been found to be effective in decreasing the incidence of candidiasis (see page 2, Encyclopedia of Alternative medicine, Yeast Infection, Treatment).

Watson et al. teach an herbal formulation where the solid component comprises of garlic bulb and pau d'arco (see abstract). Yeast overgrowth of *Candida Albicans*, a common yeast, may develop disorders such as yeast infections (see column 1, lines 34-41). The solid component may be compressed and formed into tablet, which can then be swallowed. The herbal formulation according to the present invention is designed to be taken orally (see column 2, lines 39-42). The effective daily dosage for the food supplement and herbal formulation ranges from about 100 mg per day to about 1000 mg per day for the liquid component, and from about 300 mg per day to about 2500 mg per day for the solid component (see col. 4, lines 5-9).

It is within the level of the skilled artisan to utilize various well-known ingredients such as garlic, *Lactobacillus acidophilus* and Pau d'arco to treat yeast infection. Clearly, the skilled artisan is provided with ample instruction and motivation to use garlic, acidophilus, and pau d'arco for treating yeast infection. Ford discloses a micro-encapsulated lactobacilli for treating vaginal yeast infection. Mayra-Makinen et al. disclose a probiotic combination comprising different combinations of lactobacilli, propionic acid bacteria, and/or bifidobacteria to be consumed as such or combined with a suitable foodstuff, such as a dairy product or a drink. Foster teaches Pau d'arco where it is used traditionally to treat a wide range of conditions including candidiasis (a yeast infection of the vaginal tract). Encyclopedia of alternative Medicine defines that garlic (*Allium sativum*) is believed to have antifungal action, and therefore it is used in treating vaginal yeast infection. Watson et al. teach of a formulation to treat yeast infection that does not consist of acidophilus. Although Watson et al. uses the

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formulation for cleaning the intestinal tract from yeast infection, the components of the formulation are known to treat yeast infection in the vaginal tract also, as mentioned in the above prior arts. The skilled artisan is motivated to make a formulation of the well-known ingredients, known for treating yeast infection in the vaginal tract.

Ford teach the dosage of the encapsulated lactobacilli, were given four times a day at the initiation of the antimicrobial therapy and were continued for three days after the antibiotic therapy was discontinued. The optimal dosage amounts would have been obvious to the skilled artisan. The determination of a dosage of the active ingredient are well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug while minimizing adverse or unwanted side effects or even undesirable stability issues. Thus, one of ordinary skill in the art would have been motivated to combine the teachings of the above references and as combined teach the invention as claimed.

Where the claimed and prior arts ingredients of a composition are identical a prima facie case of obviousness has been established. Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and as a whole, prima facie obvious.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner
1614

May 22, 2007


29 MAY 2007

 5/29/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER